

**Notice of Allowability**

Application No.

10/788,993

Applicant(s)

MADAR ET AL.

Examiner

Art Unit

Robert Shiao, Ph.D.

1626

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment filed on March 13, 2007.
2. ☒ The allowed claim(s) is/are 1-13 and 15-23, now are 1-22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### **DETAILED ACTION**

1. This application claims benefit of the provisional application: 60/412,084 with a filing date 09/19/2002.
2. Amendment of claims 1, 5-6, 13, 16 and 20-24 in the amendment filed on March 13, 2007 is acknowledged. The terminal disclaimer filed on February 05, 2007, is also acknowledged. Claims 1-30 are pending in the application.

### ***Responses to Amendment***

3. The rejection of claims 1-24 under 35 U.S.C. 112, first paragraph has been overcome in the amendment filed on March 13, 2007.
4. Since the variable R<sub>1</sub> of formula (I) of instant claims 1-24 represents alkyl (i.e., methyl) when the variable R is cyano, the rejection of claims 1-24 under 35 U.S.C. 103(a) is maintained.
5. Since the terminal disclaimer has been filed and approved in the Office, the provisional rejection of claims 1-24 under the obviousness-type double patenting over Madar et al. co-pending application No. 11/036,258 has been overcome.

### ***EXAMINER'S AMENDMENT***

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew M. Parial on April 18, 2007. The following non-elected subject matter has been deleted and based on the restriction requirement, dated March 27, 2006. The application has been amended as follows:

In claim 1, line 6, delete "heterocyclecarbonyl,"

In claim 1, page 3, line 2, after "arylalkyl", delete ":"

In claim 1, page 3, lines 3-8, delete "R<sub>A</sub> and R<sub>B</sub> are each independently selected from the group consisting of alkyl, alkylcarbonyl, alkoxy carbonyl, alkylsulfonyl; or R<sub>A</sub> and R<sub>B</sub> taken together with the nitrogen to which they are attached form a ring selected from the group consisting of piperidine, piperazine and morpholine; and R<sub>C</sub> and R<sub>D</sub> are each independently selected from the group consisting of hydrogen and alkyl", and insert  
--, with a proviso when R is cyano, X is CH<sub>2</sub>, and R<sub>1</sub> is alkyl, wherein the alkyl is not methyl--

In claim 9, lines 7-8, after "hydrogen", delete ". aryl, and heterocycle", and insert  
-- and aryl--

In Claim 16, lines 7-8, delete "(2S,5R)-5-ethynyl-1-(N-(tetrahydrofuran-2-ylmethyl)glycyl)pyrrolidine-2-carbonitrile;"

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In claim 17, lines 10-11, after "alkylcarbonyl", delete ", aryl and heterocycle", and insert

-- and aryl--"

In claim 19, lines 9-10, after "arylcarbonyl", delete "and heterocyclecarbonyl"

Delete claim 14

Delete claims 24-30.

### ***Reasons for Allowance***

7. The following is an examiner's statement of reasons for allowance:

Claims 1-13 and 15-23 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to Pharmaceutical compositions as Inhibitors of dipeptidyl peptidase-IV (DPP-IV). The closest reference is Villhauer's US 6,011,155, which discloses N-(substituted glycyI)-2-cyanopyrrolidines, pharmaceutical compositions containing them and their use in inhibiting dipeptidyl peptidase-IV. The difference between the reference and instant claims is that instant claimed compounds of formula (I) have not been found. A suggestion for modification of above reference to obtain the instant claimed compounds/compositions has not been found. Claims 1-13 and 15-23 are allowed.

Any comments considered necessary by applicant must be submitted no later

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than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

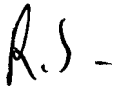
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Joseph K. McKane  
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Robert Shiao, Ph.D.  
Patent Examiner  
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March 19, 2007